



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,845	03/30/2004	Stephen D. Pacetti	50623.00343	6042

7590 08/19/2005

Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
----------	--------------

1734

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,845

Applicant(s)

STEPHEN D. PACETTI

Examiner

Laura Edwards

Art Unit

1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Withdrawn Allowable Subject Matter

The indicated allowability of claims 5, 6, 10, 13, 14, 18, 21, and 22 are withdrawn in view of the newly discovered reference(s) as set forth below. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 7-9, 11, 15-17, 19, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) coating chamber (12) and a pressure controller (34) wherein the apparatus enables a coating composition to be deposited on an implantable device at a desired pressure (see col. 5, lines 7-8). Even though Shim et al are silent concerning means for applying a coating composition comprising a coating solvent to the implantable device, it was known in the art, at the time the invention was made, to coat an implantable device with a solvent based coating composition using a CVD type coating chamber as evidenced by Sass (see col. 5, lines 59 to col. 6, line 25). In light of the teachings of Sass, it would have been obvious to one of ordinary skill in the art to utilize the Shim et al CVD coating chamber for coating an implantable device with a desired coating composition even one which is solvent based. Furthermore, the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent has not been given patentable weight because such a recitation is deemed a user

Art Unit: 1734

manipulative step. It is well established as evidenced by Shim et al to control the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4). Therefore, it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

With respect to claim 3, Shim et al recognize the implantable device (24) being placed on an electrode or support.

With respect to claim 7, see col. 6, lines 44+.

With respect to claim 8, see col. 4, lines 60-64.

With respect to claims 9 and 17, the apparatus of Shim et al provides a pressure controller or regulating valve capable of adjusting pressure within the coating chamber in accordance with coating film characteristics.

Claims 2, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) as applied to claims 1, 9, and 17 above and further in view of Vaartstra et al (US 6,435,798).

The teachings of Shim et al and Sass have been mentioned above but neither teach or suggest an applicator for spraying the coating composition at the implantable device. However, it was known in the art at the time the invention was made to provide a showerhead (50) in communication with an atomizer in a CVD apparatus to spray a reactive coating composition onto the surface of the device being treated in the CVD chamber as evidenced by Vaartstra et al (see Fig. 1). It would have been obvious to one of ordinary skill in the art to provide a spraying

Art Unit: 1734

applicator system as taught by Vaartstra et al in the apparatus as defined by the combination above in order to evenly distribute the coating about the surface of the device. The use of a spraying applicator system to evenly distribute or spread the coating composition about the surface of the device in a CVD chamber is within the purview of one skilled in the art.

Claims 4, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 1, 9, and 17 above, and further in view of Vallana et al (US 5,370,684).

The teachings of Shim et al and Sass have been mentioned above but neither Shim et al nor Sass teach a means for rotating the implantable device during coating. However, it was known in the art, at the time the invention was made, to provide in a CVD coating chamber, a rotatable support for rotating an implantable device during coating as evidenced by Vallana et al (see col. 7, lines 39-43). It would have been obvious to one of ordinary skill in the art to provide a rotational support as taught by Vallana et al in the CVD coating chamber of Shim et al in order to provide even coverage of coating about the entire surface of the implantable device.

Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 9 and 17 above, and further in view of Leidner et al (US 6,056,993).

The teachings of Shim et al and Sass have been mentioned above but neither Shim et al nor Sass teach a means for moving the device in a linear direction during coating. However, it was known in the art, at the time the invention was made, to provide in a coating chamber a

Art Unit: 1734

means for moving an implantable device along a linear direction during coating to enable a desired thickness of coating to be applied on the device via sufficient passes or movement of the implantable device relative to the application means as evidenced by Leidner et al (see col. 7, lines 21-35). It would have been obvious to one of ordinary skill in the art to provide a means for moving an implantable device along a linear direction during coating as taught by Leidner et al in the apparatus as defined by the combination above in order to provide a desired coating thickness on the implantable device.

Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 1 and 9 above, and further in view of Bergmann (US 5,855,684).

The teachings of Shim et al and Sass have been mentioned above but neither Shim et al nor Sass teach a means for creating convection flow within the chamber. However, it was known in the art, at the time the invention was made, to provide a means for creating convection flow in a CVD chamber in order to increase the efficiency of the coating process as evidenced by Bergmann (see col. 3, lines 33-45 and col. 4, lines 46-64). It would have been obvious to one of ordinary skill in the art to provide the convection flow means as taught by Bergmann in the apparatus as defined by the combination above in order to increase the efficiency of the coating process.

Claims 25, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) and Leidner et al (US 6,056,993).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) coating chamber (12) and a pressure controller (34) wherein the apparatus enables a coating composition to be deposited on an implantable device at a desired pressure (see col. 5. lines 7-8). Shim et al are silent concerning the CVD chamber being capable of coating the implantable device with a solvent based coating composition and the chamber including a linear moving means. However, it was known in the art, at the time the invention was made, to coat an implantable device with a solvent based coating composition using a CVD type coating chamber as evidenced by Sass (see col.5, lines 59 to col. 6, line 25). In light of the teachings of Sass, it would have been obvious to one of ordinary skill in the art that the Shim et al CVD coating chamber would be capable of coating an implantable device with a desired coating composition even one which is solvent based. Also, it was known in the art, at the time the invention was made, to provide in a coating chamber a means for moving an implantable device along a linear direction during coating to enable a desired thickness of coating to be applied on the device via sufficient passes or movement of the implantable device relative to the application means as evidenced by Leidner et al (see col. 7, lines 21-35). It would have been obvious to one of ordinary skill in the art to provide a means for moving the implantable device along a linear direction during coating as taught by Leidner et al in the apparatus as defined by the combination above in order to enable sufficient passes or movement of the implantable device relative to the application means to provide a desired coating thickness on the implantable device. As for the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent, this recitation has been given no patentable weight because controlling of the pressure within the chamber based on the solvent used in the coating

Art Unit: 1734

composition is deemed a user manipulative step. It is well established as evidenced by Shim et al to control the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4). Therefore, it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

Claims 26, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) and Bergmann (US 5,855,684).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) coating chamber (12) and a pressure controller (34) wherein the apparatus enables a coating composition to be deposited on an implantable device at a desired pressure (see col. 5, lines 7-8). Shim et al are silent concerning the CVD chamber being capable of coating the implantable device with a solvent based coating composition and the chamber including means for creating convection flow. However, it was known in the art, at the time the invention was made, to coat an implantable device with a solvent based coating composition using a CVD type coating chamber as evidenced by Sass (see col.5, lines 59 to col. 6, line 25). in light of the teachings of Sass, it would have been obvious to one of ordinary skill in the art that the Shim et al CVD coating chamber would be capable of coating an implantable device with a desired coating composition even one which is solvent based. Also, it was known in the art, at the time the invention was made, to provide a means for creating convection flow in a CVD chamber in order to increase the efficiency of the coating process as evidenced by Bergmann (see col. 3, lines 33-45 and col. 4, lines 46-64). It would have been obvious to one of ordinary

Art Unit: 1734

skill in the art to provide the convection flow means as taught by Bergmann in the apparatus as defined by the combination above in order to increase the efficiency of the coating process. The recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent has not been given no patentable weight because controlling of the pressure within the chamber based on the solvent used in the coating composition is deemed a user manipulative step. As recognized by Shim et al, controlling of the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4) is well established such that it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) and Vaartstra et al (US 6,244,575).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) coating chamber (12) and a pressure controller (34) wherein the apparatus enables a coating composition to be deposited on an implantable device at a desired pressure (see col. 5, lines 7-8). Shim et al are silent concerning the CVD chamber being capable of coating the implantable device with a solvent based coating composition or an applicator for spraying the coating composition at the implantable device. However, it was known in the art, at the time the invention was made, to coat an implantable device with a solvent based coating composition using a CVD type coating chamber as evidenced by Sass (see col.5, lines 59 to col. 6, line 25). In light of the teachings of Sass, it would have been obvious to one of ordinary skill

Art Unit: 1734

in the art that the Shim et al CVD coating chamber would be capable of coating an implantable device with a desired coating composition even one which is solvent based. Also, it was known in the art at the time the invention was made to provide a showerhead (50) in communication with an atomizer in a CVD apparatus to spray a reactive coating composition onto the surface of the device being treated in the CVD chamber as evidenced by Vaartstra et al (see Fig. 1). It would have been obvious to one of ordinary skill in the art to provide a spraying applicator system as taught by Vaartstra et al in the apparatus as defined by the combination above in order to evenly distribute the coating about the surface of the device. The use of a spraying applicator system as to evenly distribute or spread the coating composition about the surface of the device in a CVD chamber is within the purview of one skilled in the art. As for the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent, this recitation has been given no patentable weight because controlling of the pressure within the chamber based on the solvent used in the coating composition is deemed a user manipulative step. As recognized by Shim et al, controlling of the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4) is well established such that it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patent discloses the state of the art with respect to CVD or plasma

Art Unit: 1734

apparatus incorporating a showerhead or sprayer for even application of fluid onto a surface of a substrate: See Satoh (US 6,435,798)- col. 7, lines 35-42.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards
Primary Examiner
Art Unit 1734

Le
August 17, 2005